



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,584	08/03/2001	Keisuke Kuida	VPI00-115 CIP	9797

7590 11/13/2003

Andrew S. Marks  
VERTEX PHARMACEUTICALS INC.  
130 Waverly Street  
Cambridge, MA 02139-4242

EXAMINER
----------

SHUKLA, RAM R

ART UNIT	PAPER NUMBER
----------	--------------

1632

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/922,584

Applicant(s)

KUIDA ET AL.

Examiner

Ram R. Shukla

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 20-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 20-23 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Applicant's election without traverse of the invention of group VI (claims 20-21) in the paper filed 8-28-03 is acknowledged.
2. New claims 22 and 23 and amendments to claims 20-21 have been entered.

### ***Election/Restrictions***

3. In view of applicants' amendment to claims 20 and 21 and newly presented claims 22 and 23, a new restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 20-23, drawn to a method of treating angiogenesis by administering an antibody specific to Erk5 protein and an additional therapeutic agent, classified in class 424, subclass 184.1.
  - II. Claims 20-23, drawn to drawn to a method of treating angiogenesis by administering an oligonucleotides that specifically hybridizes to Erk5 DNA and prevents transcription of Erk5 transcription and an additional therapeutic agent, classified in class 514, subclass 44.
  - III. Claims 20-23, drawn to drawn to a method of treating angiogenesis by administering an oligonucleotides that specifically hybridizes to Erk5 mRNA and prevents translation of Erk5 and an additional therapeutic agent, classified in class 514, subclass 44.
  - IV. Claims 20-23, drawn to drawn to a method of treating angiogenesis by administering a ribozyme that cleaves Erk5 mRNA and an additional therapeutic agent, classified in class 514, subclass 44.
  - V. Claims 20-23, drawn to a method of treating angiogenesis by administering a small molecule inhibitor and an additional therapeutic agent, classified in class 514, subclass 1.
  - VI. Claims 20-23, drawn to a method of treating angiogenesis by administering an antagonist of Erk5 protein and an additional therapeutic agent, classified in class 514, subclass 1.

Art Unit: 1632

4. Claims 20 and 21 link inventions of the groups I-VI. The restriction requirement between the linked inventions is subject to the non-allowance of the linking claim(s), claims 20 and 21. Upon the allowance of the linking claims, the restriction requirement as to the linked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application.

Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or non-statutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 USC 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129,131-132 (CCPA 1971). See also MPEP 804.01.

5. Claim 23 IS generic to a plurality of disclosed patentably distinct species comprising more than 25 species. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. The inventions of the groups I-VI are patentably distinct each from the other because they are drawn to methods of treatment that use distinct steps and the compositions used in the methods have different structure, function, effects and mode of operation. For example, the structure of the oligonucleotides will be different from that of an antibody or an antagonist or a ribozyme or a small molecule inhibitor. Additionally, the oligonucleotides of the groups II and III will

Art Unit: 1632

have different sequence structure compared to each other and oligo used in one method cannot be used in the other method. Furthermore, the mode of operation of the compositions used in the groups I-VI will also be different. For example, an oligo of group II inhibits transcription while the oligo of group III inhibits translation and the ribozyme of group IV degrades mRNA. Therefore, the inventions of the groups I-IV are patentably distinct each from the other and the search for one group will not be coextensive with the search of any of the other groups.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art shown by their different classification and/ or their recognized divergent subject matter, and because each invention requires a separate, non-coextensive search, restriction for examination purposes as indicated is proper.

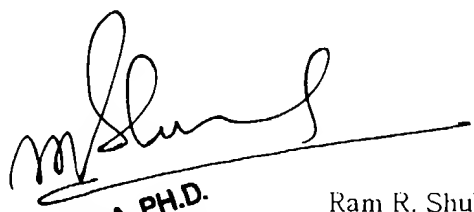
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ram R. Shukla whose telephone number is (703) 305-1677. The examiner can normally be reached on Monday through Friday from 7:30 am to 4:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051. The fax phone number for TC 1600 is (703) 703-872-9306. Any

Art Unit: 1632

inquiry of a general nature, formal matters or relating to the status of this application or proceeding should be directed to the William Phillips whose telephone number is (703) 305-3413.



**RAM R. SHUKLA, PH.D.**  
**PRIMARY EXAMINER**

Ram R. Shukla, Ph.D.  
Primary Examiner  
Art Unit 1632